UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
Galveston Division

TEXAS DEPARTMENT OF CRIMINAL JUSTICE, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	)	Case No. 3:17-cv-00001

DEFENDANTS' AMENDED ANSWER TO
PLAINTIFF'S SECOND AMENDED COMPLAINT

Answering specifically the numbered paragraphs of the Complaint filed by Plaintiff, Texas Department of Criminal Justice (TDCJ, or Texas), Defendants state as follows:

INTRODUCTION

1. Paragraph 1 consists of Plaintiff's characterization of this action and conclusions of law, to which no response is required.

JURISDICTION AND VENUE

2. Paragraph 2 consists of statements and conclusions of law, to which no response is required.

3. Defendants admit that the drugs at issue in this action are being held in this District. The remaining allegations in Paragraph 3 consist of statements and conclusions of law, to which no response is required.

PARTIES

4. Defendants deny the allegations in Paragraph 4 for lack of knowledge or information sufficient to form a belief as to the truth of the matters asserted.

5. With respect to the first sentence of paragraph 5, Defendants admit the drugs at issue in this case are subject to the requirements of the Federal Food, Drug, and Cosmetic Act and that the United States Food and Drug Administration (FDA) has refused admission of those drugs into domestic commerce. With respect to the second sentence of Paragraph 5, Defendants admit that Scott Gottlieb, M.D. is the Commissioner of Food and Drugs. With respect to the third sentence of Paragraph 5, Defendants admit that Dr. Gottlieb is named in his official capacity. The remaining allegations in Paragraph 5 consist of Plaintiff's characterization of this action and conclusions of law, to which no response is required.

6. The allegations in Paragraph 6 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

7. The allegations in Paragraph 7 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

8. The allegations in Paragraph 8 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

9. Sentences one, three, and four of Paragraph 9 attempt to characterize 21 U.S.C. §§ 321(p) and 355; Defendants aver that the text of those provisions is the best evidence of their contents. The remaining allegations in Paragraph 9 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

10. The allegations in Paragraph 10 constitute statements and conclusions of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

11. Sentences one and two of Paragraph 11 constitute statements and conclusions of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents. With respect to sentence three, Defendants admit that FDA has issued the regulations at 21 C.F.R. Parts 330-358 and that 21 C.F.R. § 330.1(a) states, in part, "[a]n over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not

misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph." Defendants further state that sodium thiopental is not an OTC drug and is not the subject of any OTC drug monograph. With respect to sentence four, Defendants admit that numerous OTC drugs that satisfy all of the applicable requirements in FDA's regulations are marketed without submitting a new drug application or abbreviated new drug application to FDA; the remaining allegations of that sentence consist of Plaintiff's statements and conclusions of law, to which no response is required.

12. The allegations in Paragraph 12 constitute statements and conclusions of law, to which no response is required.

13. With respect to the first sentence of Paragraph 13, Defendants admit that an unapproved new drug may also be misbranded under 21 U.S.C. § 352(f)(1). The remaining allegations in Paragraph 13 constitute statements and conclusions of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

14. The allegations in Paragraph 14 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

15. The allegations in sentence one of Paragraph 15 constitute statements of law, to which no response is required. With respect to sentence two, Defendants admit that FDA has issued regulations at 21 C.F.R. Part 201 Subpart D – Exemptions from Adequate Directions for Use. Defendants aver that the text of those regulations is the best evidence of their contents.

16. With respect to sentence one of Paragraph 16, Defendants admit that FDA concluded that drugs at issue in this action do not qualify for the exemption in 21 C.F.R.

§ 201.125. The remaining allegations in Paragraph 16 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory and regulatory provisions, Defendants aver that the statutes' and the regulations' text is the best evidence of their contents.

17. Defendants deny the allegations in Paragraph 17.

18. The allegations in Paragraph 18 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of a statutory provision, Defendants aver that a statute's text is the best evidence of its contents.

19. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 19 because FDA determined it was not necessary to reach a final decision on whether the drugs at issue appear to be misbranded within the meaning of 21 U.S.C. § 352(f)(2).

20. Defendants admit the first sentence in Paragraph 20. With respect to sentence two, Defendants admit that FDA's roles include evaluating whether drugs that are offered for import should be admitted into domestic commerce and aver that the remaining allegations constitute statements and conclusions of law, to which no response is required.

21. The allegations in the first sentence of Paragraph 21 constitute statements and conclusions of law, to which no response is required. With respect to sentence two, Defendants admit that FDA collects samples of FDA-regulated products. With respect to sentence three, Defendants admit that when FDA decides to collect a sample, FDA issues a Notice of FDA Action indicating intention to collect a sample and stating that the product should be held intact pending the results of such sampling. Defendants deny the allegations in sentence four.

22. The allegations in Paragraph 22 constitute statements of law, to which no response is required. To the extent that the Plaintiffs are summarizing the contents of statutory provisions, Defendants aver that a statute's text is the best evidence of its contents.

23. With respect to the first sentence of Paragraph 23, Defendants admit that if it "appears from the examination of such samples or otherwise" that the imported drugs are in violation of criteria set forth in 21 U.S.C. § 381(a), FDA may issue a Notice of FDA Action stating that the imported drugs are subject to refusal and giving notice of the opportunity to provide testimony. Sentence two attempts to characterize 21 U.S.C. § 381(a) and 21 C.F.R. § 1.94(a); Defendants aver that the text of those statutory and regulatory provisions is the best evidence of their contents. With respect to sentences three and four, Defendants admit that, if FDA determines that a shipment of imported drugs should not be refused admission, FDA issues a Notice of FDA Action releasing the drugs, and if FDA determines that the shipment should be refused admission, it issues a Notice of FDA Action refusing admission. Sentence five of Paragraph 23 consists of statements and conclusions of law, to which no response is required.

24. The allegations in sentences one and three of Paragraph 24 constitute statements and conclusions of law, to which no response is required. With respect to sentence two, Defendants admit that a Notice of FDA Action refusing admission reflects FDA's determination that the product is not admissible into the United States.

25. With respect to the first sentence of Paragraph 25, Defendants admit that, if FDA refuses admission, FDA works with U.S. Customs and Border Protection to help ensure the proper disposition of the shipment. With respect to the remaining sentences in this paragraph, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegation regarding the general practices of Customs and Border Protection, which is not named

as a Defendant in this lawsuit. To the extent that Plaintiff purports to summarize the contents of a statute and Customs' regulations, those summaries constitute statements and conclusions of law, to which no response is required; furthermore, Defendants aver that the cited statute and regulations are the best evidence of their own contents.

26. With respect to the first sentence of Paragraph 26, Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegation regarding the practices of Customs and Border Protection, which is not named as a Defendant in this lawsuit, but admit that FDA may sometimes take possession of a detained product. With respect to sentence two of Paragraph 26, Defendants admit that if FDA refuses admission, FDA works with Customs and Border Protection to help ensure the proper disposition of the shipment.

27. Defendants admit the allegations contained in the first sentence of Paragraph 27. With respect to sentence two, Defendants admit that PREDICT uses historical data and has the ability to use pattern anomalies to create a different risk score for every import line within an import entry involving products regulated by FDA that are transmitted electronically. With respect to sentence three, Defendants admit that PREDICT assigns a risk percentile to every import line based in part on information stored in FDA databases, including but not limited to, information regarding the compliance history of the foreign manufacturer. With respect to sentence four, Defendants admit that the risk percentile is calculated based on different risk modifiers. Defendants deny the allegations in sentence five of Paragraph 27. With respect to sentence six, Defendants admit that imported products determined by PREDICT to be higher risk are flagged for review by FDA personnel.

28. With respect to sentence one of Paragraph 28, admit that when FDA refuses an import entry of drugs, the refusal is entered into FDA's OASIS database and is part of the

compliance history of the drugs' manufacturer. Defendants deny the allegations contained in sentences two and three of Paragraph 28. With respect to sentence four, Defendants admit that, generally speaking, an increase in risk percentile of the line the manufacturer is on could increase the likelihood of a manual review by FDA personnel for future imports. Defendants aver, however, that none of Plaintiffs' allegations regarding PREDICT are relevant to this matter because all shipments of sodium thiopental are subject to manual review.

29. Paragraph 29 consists of Plaintiff's characterization of this action, to which no response is required.

30. With respect to the first sentence of Paragraph 30, Defendants admit that sodium thiopental is a barbiturate that depresses the nervous system function to render a person unconscious and that it is classified as an ultrashort-acting anesthetic. With respect to the second sentence, Defendants admit that the well-known uses of sodium thiopental include use as an anesthetic and in lethal injection. Defendants admit the allegations of sentence three of Paragraph 30, but state that sodium thiopental is no longer widely used by hospitals as a prescription anesthetic. Defendants admit the allegations in sentence four.

31. Defendants admit that it has been reported that Texas has previously used thiopental sodium in numerous executions, but deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 31.

32. With respect to sentence one of Paragraph 32, Defendants admit that on January 5, 2011, FDA's Division of Import Operations sent procedures to FDA field offices titled "Guidance for handling pending and future shipments of Sodium Thiopental." Defendants admit the allegations in sentence two of Paragraph 32. The allegations in sentence three of Paragraph 32 contain statements and conclusions of law, to which no response is required.

33. The allegations of Paragraph 33 purport to summarize the contents of the procedures that FDA's Division of Import Operations sent to FDA field offices on January 5, 2011; Defendants aver that the text of those procedures is the best evidence of its contents.

34. With respect to sentence one of Paragraph 34, Defendants admit that FDA's Division of Import Operations retracted the January 5, 2011, procedures on March 28, 2012. With respect to sentence two, Defendants admit that the Division of Import Operations issued updated instructions and procedures for import entries for sodium thiopental on April 16, 2012. With respect to sentence three, Defendants aver that the Division of Import Operations was previously called the Division of Import Operations and Policy. Defendants deny the allegations in sentence four. With respect to sentence five, Defendants admit that the April 16, 2012, document, as amended September 5, 2012, continues to serve as the agency's instructions and procedures for its field offices for import entries for sodium thiopental, but deny that either version is a binding rule.

35. The allegations in Paragraph 35 purport to summarize the instructions and procedures for import entries for sodium thiopental that FDA's Division of Import Operations distributed to FDA's field offices on April 16, 2012. That document is the best evidence of its own contents.

36. With respect to the first sentence of Paragraph 36, Defendants admit that the labels of the drugs at issue state, in part, "Thiopental Sodium USP" and "For law enforcement purpose only," but aver that the labels are the best evidence of their contents. Defendants deny the allegations in sentence two. With respect to sentence three, Defendants admit that the manufacturer identified on the label of the detained drugs registered with FDA and listed

thiopental sodium USP; the remaining allegations in sentence three of Paragraph 36 constitute conclusions of law, to which no response is required.

37. With respect to the first sentence of Paragraph 37, Defendants admit that the labels of the drugs at issue state, in part, "Rx Only" and "CIII," but aver that the labels are the best evidence of their contents. With respect to sentence two, Defendants admit that TDCJ has provided FDA with a copy of a United States Drug Enforcement Administration (DEA) registration certificate but state that such certificate expired November 30, 2015. Defendants deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 37.

38. Defendants admit the allegations in Paragraph 38, but deny that the quoted statement represents FDA's interpretation of the June 22, 2012 Order issued in *Beaty v. FDA*, Civ. No. 1:11-cv-00289 (RJL) (D.D.C.) as to all potential sodium-thiopental drug products.

39. Defendants admit that TDCJ filed a Controlled Substance Import Declaration on June 8, 2015. The remaining allegations in Paragraph 39 purport to summarize that document, and Defendants aver that the text of that document is the best evidence of its contents.

40. Defendants admit that the DEA issued a letter to TDCJ dated July 13, 2015. To the extent Plaintiff purports to summarize the contents of that letter, Defendants aver that the text of that letter is the best evidence of its contents.

41. With respect to sentences one and two of Paragraph 41, Defendants admit that a foreign distributor shipped 1000 vials labeled, in part, as Thiopental Sodium USP via air freight to TDCJ, which was received at Houston Intercontinental Airport, in Houston, Texas. Defendants admit that the Notice of FDA Action issued on August 24, 2015 states that the "arrival date" of the shipment was July 24, 2015 and that the "date received" was July 27, 2015.

Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in sentence three of Paragraph 41.

42. Defendants admit the allegations in sentence one of Paragraph 42. With respect to sentence two, Defendants admit that FDA issued a Notice of FDA Action on July 29, 2015, which was rescinded on July 30, 2017. With respect to sentences two and three of Paragraph 42, Defendants admit that U.S. Customs and Border Protection issued a Notice of Detention for the import entry on August 5, 2015, and state that the remaining allegations purport to summarize the Notice of Detention, which is the best evidence of its own contents.

43. Defendants admit that on August 24, 2015, FDA issued a Notice of FDA Action stating that the import entry was subject to refusal and giving notice of the opportunity provide testimony. The remaining allegations of Paragraph 43 purport to summarize information in FDA's August 24, 2015, Notice of FDA Action, which is the best evidence of its own contents.

44. Defendants admit that on October 23, 2015, TDCJ, through counsel, submitted a letter and exhibits on behalf of the detained sodium thiopental. The remaining allegations of Paragraph 44 purport to summarize information in TDCJ's October 23, 2015 letter to FDA, which is the best evidence of its own contents.

45. The allegations of Paragraph 45 purport to summarize information in TDCJ's October 23, 2015 letter to FDA, which is the best evidence of its own contents.

46. The allegations of Paragraph 46 purport to summarize information in TDCJ's October 23, 2015 letter to FDA, which is the best evidence of its own contents.

47. The allegations of Paragraph 47 purport to summarize information in TDCJ's October 23, 2015 letter to FDA, which is the best evidence of its own contents.

48. Defendants admit the allegations in the first sentence of Paragraph 48. The allegations of sentence two of Paragraph 48 purport to summarize information in FDA's April 15, 2016 letter to Plaintiffs' counsel, which is the best evidence of its own contents.

49. Defendants admit that TDCJ submitted a response to FDA's April 15, 2016 letter on May 20, 2016. The remaining allegations of Paragraph 49 purport to summarize information in TDCJ's May 20, 2016 letter to FDA, which is the best evidence of its own contents.

50. Defendants admit that on April 21, 2017 FDA issued a Notice of FDA Action refusing admission to the drugs at issue and that the refused sodium thiopental presently remains in the custody of FDA, in Houston, Texas. The remaining allegations of Paragraph 50 purport to summarize information in the April 21, 2017 Notice of FDA Action, which is the best evidence of its own contents.

51. The allegations of Paragraph 51 purport to summarize information in FDA's April 20, 2017 Letter to Plaintiffs' counsel, which is the best evidence of its own contents.

52. Defendants admit that the April 21, 2017 Notice of FDA Action was issued by an FDA Compliance Officer on behalf of FDA, and that FDA's April 20, 2017 letter to Plaintiffs' counsel was signed by the Acting Director of FDA's Division of Southwest Imports. Defendants further admit that the April 20, 2017 letter and the April 21, 2017 Notice of FDA Action reflect FDA's final determination on the admissibility of the drugs at issue. The remaining allegations in Paragraph 52 constitute statements and conclusions of law, to which no response is required.

53. The allegations in Paragraph 53 constitute statements and conclusions of law, to which no response is required.

54. Defendants admit that FDA's decision to refuse admission to the Thiopental Sodium USP that TDCJ is seeking to import represents FDA's final determination on the

admissibility of the drugs at issue and prevents the drugs from entering domestic commerce. The remaining allegations in Paragraph 54 constitute statements and conclusions of law, to which no response is required.

55. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 55 and further state that the allegations in Paragraph 55 constitute statements and conclusions of law, to which no response is required.

56. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 and further state that the allegations in Paragraph 56 constitute statements and conclusions of law, to which no response is required.

57. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence of Paragraph 57, and further state that those allegations constitute statements and conclusions of law, to which no response is required. Sentence two purports to summarize information in FDA's April 20, 2017 letter to Plaintiffs' counsel, which is the best evidence of its own contents. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in sentence three concerning the effect that the FDA's letter will have on TDCJ's reputation, and further state that, to the extent sentence three purports to summarize the FDA's letter, that letter is the best evidence of its own contents. The remaining allegations in Paragraph 57 constitute statements and conclusions of law, to which no response is required.

58. The allegations in sentences one, eight, and nine of Paragraph 58 constitute statements and conclusions of law, to which no response is required. Defendants deny the allegations in sentence seven. Defendants deny knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 58.

59. The allegations in sentence one of Paragraph 59 constitute statements and conclusions of law, to which no response is required, and purport to summarize the 2012 DIOP Procedure, which is the best evidence of its own contents. With respect to sentence two, Defendants admit that when FDA refuses an import entry of drugs, the refusal is entered into FDA's OASIS database and is part of the compliance history of the drugs' manufacturer, but deny the remaining allegations in Paragraph 59.

60. With respect to the first sentence of Paragraph 60, Defendants admit that FDA manually reviews shipments of sodium thiopental that are imported or offered for import; the remaining allegations in sentence one and the allegations in sentence three of Paragraph 60 constitute statements and conclusions of law, to which no response is required. With respect to sentence two, Defendants admit that there have been communications between FDA and DEA regarding thiopental sodium. With respect to the sentences four and five in Paragraph 60, Defendants state that because sodium thiopental is an FDA regulated product, FDA would be notified of import entries of sodium thiopental, independent of any action by DEA. Defendants state further that FDA makes its import decisions independent of DEA.

61. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in sentences one and four concerning what actions FDA may take regarding hypothetical future shipments of sodium thiopental; the remaining allegations in sentences one, four, five, and six of Paragraph 61 constitute statements and conclusions of law, to which no response is required. Defendants deny the allegations in sentence two of Paragraph 61. With respect to sentence three, Defendants admit that FDA received TDCJ's arguments and evidence in support of the import entry on October 23, 2015 and issued its final determination regarding the admissibility of that entry on April 20, 2017.

62. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations concerning what actions FDA may take regarding hypothetical future shipments of sodium thiopental or TDCJ's expectations; the remaining allegations in Paragraph 62 constitute statements and conclusions of law, to which no response is required.

63. The allegations in Paragraph 63 constitute statements and conclusions of law, to which no response is required.

COUNT I

64. Defendants incorporate by references their responses to Paragraphs 1-63.

65. The allegations in Paragraph 65 constitute statements and conclusions of law, to which no response is required.

66. The allegations in Paragraph 66 constitute statements and conclusions of law, to which no response is required.

67. The allegations in Paragraph 67 constitute statements and conclusions of law, to which no response is required.

68. The allegations in Paragraph 68 constitute statements and conclusions of law, to which no response is required.

69. The allegations in Paragraph 69 constitute statements and conclusions of law, to which no response is required.

70. The allegations in Paragraph 70 constitute statements and conclusions of law, to which no response is required.

71. The allegations in Paragraph 71 constitute statements and conclusions of law, to which no response is required.

COUNT II

72. Defendants incorporate by references their responses to Paragraphs 1-63.

73. The allegations in Paragraph 73 constitute statements and conclusions of law, to which no response is required.

74. The allegations in Paragraph 74 constitute statements and conclusions of law, to which no response is required.

75. Defendants admit that the refused sodium thiopental is a prescription drug within the meaning of 21 U.S.C. § 353(b).

76. The allegations in the first and third sentences of Paragraph 76 constitute statements and conclusions of law, to which no response is required. Defendants deny knowledge or information sufficient to form a belief as to the truth of the allegations in sentence two of Paragraph 76.

77. The allegations in Paragraph 77 constitute statements and conclusions of law, to which no response is required.

78. The allegations in Paragraph 78 constitute statements and conclusions of law, to which no response is required.

79. The allegations in Paragraph 79 constitute statements and conclusions of law, to which no response is required.

80. The allegations in Paragraph 80 constitute statements and conclusions of law, to which no response is required.

PRAYER FOR RELIEF

The remaining allegations consist of Plaintiff's prayer for relief, to which no response is required. Defendants deny that Plaintiff is entitled to any of the relief sought in the Second Amended Complaint, or to any other relief whatsoever.

Defendants hereby specifically deny all of the allegations of the Second Amended Complaint not expressly admitted. Defendants, having fully answered plaintiff's Second Amended Complaint, pray that this action be dismissed with prejudice, and that they be granted their costs and other relief as may be appropriate.

Respectfully submitted,

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s/ Alexander V. Sverdlov
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July 7, 2017

Attorneys for Defendants

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury that on this 7th day of July, 2017, a copy of the foregoing "DEFENDANTS' AMENDED ANSWER TO PLAINTIFF'S SECOND AMENDED COMPLAINT" was filed electronically. This filing was served electronically to all parties by operation of the Court's electronic filing system.

s/ Alexander V. Sverdlov